

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OKLAHOMA**

IN RE: GENENTECH, INC.,	)	
HERCEPTIN (TRASTUZUMAB)	)	MDL DOCKET NO. 16-MD-2700
MARKETING AND SALES	)	ALL CASES
PRACTICES LITIGATION	)	

**GENENTECH, INC.'S MOTION FOR PROTECTIVE ORDER AS TO SUBPOENAS  
DUCES TECUM SERVED UPON THIRD PARTIES**

Defendant Genentech, Inc. (“Genentech”) pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, respectfully requests that this Court enter an order forbidding and/or limiting the third-party discovery requested by Plaintiffs. Plaintiffs’ broad and burdensome third-party subpoenas are improper because they go beyond Judge Kern’s Order limiting discovery and seek information that is completely irrelevant to the issue of federal preemption. Alternatively, Plaintiffs’ third-party discovery should be stayed pending a ruling from this Court on Genentech’s relevancy objections to Plaintiffs’ discovery requests.

**COMPLIANCE WITH LCvR37.1**

Genentech has complied with LCvR 37.1. Genentech’s counsel met with Plaintiffs’ counsel on September 9, 2016, and conferred in good faith. Despite a sincere attempt, the parties have been unable to reach an accord.<sup>1</sup>

---

<sup>1</sup> Additionally, Genentech notified Plaintiffs’ counsel on September 7, 2016, and again September 9, 2016, of its intent to file this Motion and requested that Plaintiffs advise all third parties that they should not produce any documents until there has been a ruling from the Court. *See* Tr. of August 26, 2016 Discovery Conference at 17:1-6 (“**THE COURT:** Okay. And then, Mr. Keglovits, when you serve those subpoenas, if you receive notice from Mr. O’Connor or Ms. Donahue that they are going to file a motion to quash, if you could just notify the third parties that they shouldn’t actually produce any documents until there’s been a ruling from the court.”). As of the filing of this Motion, Genentech has not seen any correspondence from Plaintiffs to the third parties directing them not to respond to the subpoenas.

## **FACTS**

In support of this motion, Genentech states as follows:

1. On June 24, 2016, the Court limited the first phase of discovery in this litigation to the preemption issue and authorized an early summary judgment motion. *See* Case Management Order #1 (“CMO #1”) (Dkt. 39); *see also* Tr. of June 23, 2016 Initial Case Management Conference at 26:16-20, 30:14-17 (describing the motion for summary judgment as a “threshold issue” and stating that “if it’s [an issue] that can dispose of the entire case then we need to go ahead and do that first”).

2. Genentech filed its Motion for Summary Judgment Based on Federal Preemption and Brief in Support (Dkt. 108) on August 23, 2016.

3. On September 2, 2016, Plaintiffs notified Genentech that they issued *Subpoenas Duces Tecum* on 11 third parties. The third parties are identified below.

- Patheon Pharmaceutical Services, Inc.
- Patheon Manufacturing Services LLC
- Cardinal Health
- McKesson Specialty Health
- CuraScript, Inc.
- US Oncology Pharmaceutical Services, LLC
- Oncology Therapeutics Network Corporation
- Besse Medical
- Integrated Commercialization Solutions, Inc. dba BioSolutions Direct
- ASD Specialty Healthcare, Inc.
- AmerisourceBergen Specialty Group, Inc.

4. The subpoenas directed at Patheon Pharmaceutical Services, Inc. and Patheon Manufacturing Services LLC contain the same document requests. The documents listed are:

- 1) All documents, agreements or communications involving Patheon Pharmaceutical Services and Genentech that contain or reference manufacturing or production specifications, standards, or processes for multi-dose vials of Herceptin.

- 2) All records that identify or reference any lot of Herceptin manufactured by Patheon Pharmaceutical Services that was not accepted unconditionally by Genentech.
- 3) All quality control, process control or other audits that refer or relate to the work done by Patheon Pharmaceutical Services for Genentech.
- 4) All communications from Genentech, or a person or entity acting on its behalf, to Patheon Pharmaceutical Services about either (i) target fill weight for the harvested drug substance to be used in multi-dose vials of Herceptin, or (ii) target vial fill for multi-dose vials of Herceptin.<sup>2</sup>

5. The subpoenas directed at the other nine third parties contain the same document requests. The documents listed are:

- 1) All communications, complaints or inquiries, received by You from a practice group, or made by You to Genentech about the mass, concentration, or reconstituted volume of multi-dose vials of Herceptin.
- 2) All communications, responses, and documents received from Genentech about any complaint or inquiry concerning the mass, concentration, or reconstituted volume of multi-dose vials of Herceptin.
- 3) All communications, complaints or inquiries made to the FDA about the mass, concentration, or reconstituted volume of multi-dose vials of Herceptin.
- 4) All communications, responses, and documents received from the FDA about any complaint or inquiry concerning the mass, concentration, or reconstituted volume of multi-dose vials of Herceptin.<sup>3</sup>

---

<sup>2</sup> The *Subpoenas Duces Tecum* directed at Patheon Pharmaceutical Services, Inc. and Patheon Manufacturing Services LLC are attached hereto as Exhibit 1.

<sup>3</sup> The *Subpoenas Duces Tecum* directed at the nine Herceptin distributors and/or group purchasing organizations are attached hereto as Exhibit 2.

## **LAW AND ARGUMENT**

### **A. Legal Standard**

Challenges to third-party subpoenas are governed by Rule 26 of the Federal Rules of Civil Procedure. *Price v. Pub. Serv. Co. of Oklahoma*, No. 13-CV-514-GKF-FHM, 2014 WL 3962475, at \*2–3 (N.D. Okla. Aug. 12, 2014). Rule 26(b)(1) provides that “[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense and is proportional to the needs of the case... .” Fed. R. Civ. Pro. 26(b)(1). If something is not relevant and/or there is no possibility of relevance, it is beyond the scope of legitimate discovery. *See Estes v. ConocoPhillips Co.*, No. 05-CV-445-GKF-PJC, 2008 WL 1994918, \*2 (N.D. Okla. May 5, 2008) (citing *Owens v. Sprint/United Mgmt. Co.*, 221 F.R.D. 649, 652 (D. Kan. 2004)).

Rule 26(c) authorizes this Court, “for good cause,” to issue an order “forbidding” and/or “limiting the scope of disclosure or discovery to certain matters.” Fed. R. Civ. Pro. 26(c)(1)(A) and (D). Such an order may be obtained where the information requested is not relevant. *See, e.g., Public Serv. Co. of Oklahoma v. A Plus, Inc.*, No. CIV 10-651-D, 2010 WL 4811954, \*2 (W.D. Okla. Nov. 19, 2010).

Where, as in this case, “a party objects that discovery goes beyond that relevant to the claims or defenses, ‘the court would become involved to determine whether the discovery is relevant to the claims or defenses and, if not, whether good cause exists for authorizing it so long as it is relevant to the subject matter of the action.’”

*Id.* (quoting *In re Cooper Tire & Rubber Co.*, 568 F.3d 1180, 1188-89 (10th Cir. 2009)); *see also Sun River Energy, Inc. v. Nelson, et al.*, No. 11-cv-00198-MSK-MEH, 2011 U.S. Dist. Lexis 111890, \*4 (D. Colo. Sept. 26, 2011) (“Although the motion at hand appears to challenge two subpoenas, which are typically governed by Rule 45, the motion does not actually seek to quash the subpoenas, but rather requests review of the scope of discovery sought.”).

**B. Plaintiffs' Third-Party Discovery Requests Are Beyond the Scope of CMO #1 and Not Relevant to Federal Preemption.**

This Court limited Phase I discovery to the question of federal preemption. *See* CMO #1. In its Submission in Support of Early Motion for Summary Judgment on Federal Preemption, submitted to the Court on June 20, 2016, Genentech argued that limiting discovery to the narrow threshold issue of federal preemption would promote judicial efficiency and prevent the waste of the parties' and the Court's resources. *Id.* at p. 7. Judge Kern agreed, referring to federal preemption as a "threshold issue" and stating that "if it's [an issue] that can dispose of the entire case then we need to go ahead and do that first" Tr. of June 23, 2016 Initial Case Management Conference at 26:16-20, 30:14-17.

The factual material relevant to federal preemption is contained in a small part of the universe of documents available concerning Herceptin. To address preemption, the court need only consider (1) what label and manufacturing practices the FDA has approved, and (2) whether Genentech's label and manufacturing practices comport with that approval.

Nonetheless, Plaintiffs' third-party subpoenas request a vast universe of documents from numerous third parties that have no relevance to preemption.

*1. Discovery Relevant to Preemption is Limited.*

As described in Genentech's Motion for Summary Judgment, Plaintiffs' claims are barred under "obstacle" preemption because the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations expressly allow variations in the actual weight of prescription drugs. Congress and FDA have already weighed the relevant considerations and determined that reasonable variations in net contents of prescription drugs "shall" be recognized. 21 U.S.C. § 352(b); 21 C.F.R. § 201.51(g). Nearly forty years ago, the Supreme Court interpreted the FDCA

as requiring allowances for reasonable variations, also holding that state-law challenges at odds with this requirement were preempted. *Jones v. Rath Packing Co.*, 430 U.S. 519 (1977).

The relevant legal question under obstacle preemption is whether Plaintiffs' state-law claims pose an obstacle to the purposes of federal statutes and regulations and are thus preempted. The only factual questions relevant to that legal issue are (1) what constitutes the federally-approved range for contents and concentration of the drug, and (2) whether the vials Genentech sold were within the federally-approved range. Genentech previously provided Plaintiffs with the following documents necessary to address these questions:

- The Chemistry, Manufacturing and Controls section of the initial Biologics License Application (BLA) for Herceptin submitted to and approved by FDA, which contains detailed information about the manufacturing processes, formulas, FDA-approved specifications for Herceptin, as well as responses to questions posed by FDA during its review.
- Prior Approval Supplements submitted to FDA in 2000, 2008, 2010, and 2013 seeking approval of new manufacturing sites for Herceptin drug product for distribution in the United States (as well as amendments and approval letters), which contain detailed information about the manufacturing processes for Herceptin drug product, FDA-approved specifications for Herceptin, responses to questions posed by FDA during its review, and certain correspondence with FDA.
- Each version of the final labeling (i.e., prescribing information, carton label, and vial label) for Herceptin distributed in the United States.
- Documents describing the test methods and procedures for determining protein content in Herceptin vials prior to distribution.
- The Certificates of Analysis for each lot of Herceptin distributed in the United States since January 1, 2010, which show the specific protein content for each such lot.

In addition to being barred under “obstacle” preemption, Plaintiffs' claims are barred under “impossibility” preemption because federal regulations provide that Genentech may not change its manufacturing process without prior FDA approval. “The question for ‘impossibility’ [preemption] is whether the private party could *independently* do under federal law what state law requires of it.” *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011) (citing *Wyeth v. Levine*, 555 U.S. 555, 573 (2009)) (emphasis added); *see also Mut. Pharm. Co. v. Bartlett*, 133 S. Ct.

2466 (2013); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1286-90 (10th Cir. 2013) (holding that warranty claims under Oklahoma law were preempted because the manufacturer could not unilaterally alter the labeling or composition of the drug). Genentech could not satisfy Plaintiffs’ demand under state law to ensure vials contained 440 mg without changing its manufacturing process for Herceptin and the FDA-approved specification for protein content. But as *Bartlett* held, such an outcome would be preempted because a state cannot unilaterally require something that FDA must approve. Genentech must obtain prior FDA approval for any “major changes” to Herceptin. *Bartlett*, 133 S. Ct. at 2471. The changes Plaintiffs demand would certainly be major. Federal law requires manufacturers to obtain prior FDA approval for any “changes in the qualitative or quantitative formulation, including inactive ingredients, or in the specifications provided in the approved application.” 21 C.F.R. § 601.12(b)(2)(i); *see also* 21 U.S.C. § 356a(c)(2)(A).

The only relevant factual question on “impossibility” prevention is whether the manufacturing process has been approved by the FDA. Genentech previously provided Plaintiffs with information necessary to address this question when it produced (1) the Chemistry, Manufacturing and Controls section of the initial Biologics License Application (BLA) for Herceptin and (2) the Prior Approval Supplements submitted to FDA in 2000, 2008, 2010, and 2013 seeking approval of new manufacturing sites for Herceptin drug product for distribution in the United States (as well as amendments and approval letters). Whether the changes to the manufacturing process and FDA-approved specifications demanded by Plaintiffs’ claims are of the type that could not be made without FDA approval is fundamentally a legal question governed by FDA regulations.

2. *Genentech Has Already Produced Documents Relating to Patheon Relevant to Federal Preemption.*

Plaintiffs have directed the same four document requests at both Patheon Pharmaceutical Services Inc. and Patheon Manufacturing Services LLC (Patheon is an FDA-approved contract manufacturer for Herceptin drug product). *See* Ex. 1. These requests, seek a broad range of documents, including manufacturing or production specifications, standards, or process for multi-dose vials of Herceptin, quality control and process control documents (not limited to Herceptin), all communications about target fill weight or target vial fill for multi-dose vials of Herceptin, and all records about lots of Herceptin manufactured by Patheon were not accepted unconditionally by Genentech. Notably, Genentech previously provided Plaintiffs with the following preemption-related documents:

- Certificates of Analysis for lots of Herceptin 440mg distributed in the United States since 2010, including for lots manufactured by Patheon. *See, e.g.*, GENE-PS000000115–117. These documents reflect the protein content testing performed on each lot (which is quality control testing), and show that the lots manufactured by Patheon and distributed in the United States since 2010 met the FDA-approved specification for protein content.
- The Prior Approval Supplement seeking approval of Patheon as a contract manufacturer of Herceptin 440mg drug product (as well as supplements and amendments that that Prior Approval Supplement). Those documents describe in detail the precise manufacturing specifications (*see e.g.*, GENE-PAS000000381), standards and processes (*see, e.g.*, GENE-PAS0000000332–352), including descriptions of the test methods (*see, e.g.*, GENE-PAS000000379–414) sought by Plaintiffs. Additionally, the Patheon Prior Approval Supplement contains the target vial fill specifications (GENE-PAS000000368) and the testing of certain qualification lots to demonstrate production within specification (*see, e.g.*, GENE-PAS000000030).
- FDA’s letter approving this Prior Approval Supplement. Notably, the FDA-approved protein content specification for Herceptin has never changed (as reflected in the other previously-produced Prior Application Supplements for new drug product manufacturing facilities and as confirmed by the declaration of Dana Swisher in support of Genentech’s motion for summary judgment).

To the extent Plaintiffs seek documents beyond those already produced by Genentech—which address the FDA-approved specification for protein content, quality control testing related to the FDA-approved specification for protein content, and whether lots of Herceptin 440 mg

that were distributed in the United States during the applicable timeframe and manufactured by Patheon met that specification—they seek documents with no relation to federal preemption. Patheon is a contract manufacturer and cannot make changes to the Herceptin manufacturing, specification, or labeling – unilateral or otherwise.

Finally, records for lots of Herceptin manufactured by Patheon and not unconditionally accepted by Genentech have no conceivable relevance to the legal question of federal preemption (or to the merits of warranty claims). To the extent that lots of Herceptin manufactured by Patheon were not accepted unconditionally by Genentech, they would not have been distributed, and thus would not have been received by Plaintiffs.

Where discovery requests are overly broad and their relevancy is not “readily apparent,” the party seeking discovery has the burden to show the relevancy of the requests. *See Price*, 2014 WL 396 2475, at \*3. Plaintiffs have not met that burden here, as they have made no showing that the documents requested but not already received from Genentech are relevant to the issue of federal preemption. Accordingly, a protective order forbidding discovery on Patheon entities is appropriate.

3. *The Document Requests Directed at Herceptin Distributors and/or Group Purchasing Organizations Are Not Relevant to Federal Preemption.*

Plaintiffs have also served third-party subpoenas on nine Herceptin distributors and group purchasing organizations. *See* Ex. 2. These discovery requests seek a broad range of complaints concerning the mass, concentration, or reconstituted volume of multi-dose vials of Herceptin, including complaints made to the distributors and group purchasing organizations, complaints made by the distributors and group purchasing organizations, and any responses to complaints from Genentech or FDA.

As discussed above, the only relevant factual questions on obstacle and impossibility preemption are (1) what constitutes the federally-approved range for contents and concentration of the drug, (2) whether the vials Genentech sold were within the federally-approved range, and (3) whether the manufacturing process has been approved by the FDA. Complaints concerning the mass, concentration, or reconstituted volume of multi-dose vials of Herceptin and responses thereto are simply not related in any way those factual questions. Nor do they have any relevance to the legal question of whether the changes to the manufacturing process and FDA-approved specifications demanded by Plaintiffs' claims are of the type that could not be made without FDA approval.

Again, where discovery requests are overly broad and their relevancy is not "readily apparent," the party seeking discovery has the burden to show the relevancy of the requests. *See Price*, 2014 WL 396 2475, at \*3. Plaintiffs have not met that burden here, as they have made no showing that complaints concerning the mass, concentration, or reconstituted volume of multi-dose vials of Herceptin are relevant to the issue of federal preemption. Accordingly, a protective order forbidding discovery on the third-party Herceptin distributors and group purchasing organizations is appropriate.

**C. Alternatively, Plaintiffs' Third-Party Discovery Should Be Stayed Pending a Ruling From This Court on the Threshold Issue of Relevance to Preemption.**

Plaintiffs seek discovery from third parties that is completely irrelevant to the issue of federal preemption. Further, Plaintiffs have already requested from Genentech much of the same material they now seek from third parties. Genentech has repeatedly objected to these overlapping requests as irrelevant to preemption and beyond the scope of CMO #1. The dispute over the threshold question of the relevancy of the documents Plaintiffs seek remains unresolved and part of ongoing discussion regarding discovery. The parties will be filing a joint submission

on the issue. It thus makes little sense at this stage of the litigation to require third parties to undertake a far-reaching search for documents in an attempt to satisfy Plaintiffs' broad and burdensome discovery requests until the Court has ruled on whether those requests are even relevant to preemption. Accordingly, in the alternative Genentech requests that, the Court stay Plaintiffs' third-party discovery pending the joint submission and a ruling on Genentech's relevancy objections to Plaintiffs' discovery requests.

### **CONCLUSION**

For these reasons, Genentech respectfully requests the Court enter an order forbidding, limiting, and/or staying the third-party discovery requested by Plaintiffs.

Respectfully submitted,

/s/ William W. O'Connor

WILLIAM W. O'CONNOR, OBA No. 13200

**NEWTON, O'CONNOR, TURNER & KETCHUM**

15 W. 6th Street, Suite 2700

Tulsa, OK 74119

Telephone: (918) 587-0101

Facsimile: (918) 587-0102

Email: boconnor@newtonconnor.com

-and-

ALICIA J. DONAHUE, Bar No. 117412

*(admitted pro hac vice)*

**SHOOK, HARDY & BACON LLP**

One Montgomery, Suite 2700

San Francisco, CA 94104

Telephone: (415) 544-1900

Facsimile: (415) 391-0281

Email: adonahue@shb.com

JAMES P. MUEHLBERGER, Bar No. 51346

*(admitted pro hac vice)*

**SHOOK, HARDY & BACON LLP**

2555 Grand Blvd.

Kansas City, MO 64108

Telephone: (816) 474-6550

Facsimile: (816) 421-5547

Email: jmuehlberger@shb.com

*Attorneys for Defendant Genentech, Inc.*

**CERTIFICATE OF SERVICE**

I hereby certify that on the 13th day of September, 2016, the foregoing document was electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ William W. O'Connor

William W. O'Connor